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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,241	12/02/2003	Herwig Janssen	00-40374-USC	3525

7590

07/03/2006

Reed Smith LLP  
2500 One Liberty Place  
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EXAMINER
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LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/726,241

Applicant(s)

JANSSEN ET AL.

Examiner

NEIL LEVY

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-9,11-23,26 and 75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-23,26 and 75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/10/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-9,11 –23,26 & 75 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: Claim 1 does not have an explanation for R. claim 1 needs a period.

Structure of Claim 1 is missing a METHYL attached to the N-cyclic group; neither is this in the specification, but the dependent claims identify this compound as an agent consisting of spinosyn A &/or D, which spinosyn contain the methyl moiety.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Art Unit: 1615

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-9,12,14 –19,21-23,& 75 are rejected under 35 U.S.C. 102(a & e) as being clearly anticipated by Snyder 6,063,771.

.Shampoo, water, spinosyns, Spinosad(col. 3, lines 25-28), stabilizer, as suspending agent are used as hair care compositions to control Lice (claim 10, and col.2, lines 19-53, col.4, lines 21-28) with other cosmetically acceptable compounds. See example 7: cetyl and stearyl alcohol emulsion stabilizers and viscosity increasers of the instant claims 15,17,18,19,22,23, 75 ,Hydroxy ethyl cellulose @ .5% the stabilizers of instant claims 1,12. Glyceryl monostearate moisturizer ,cetearth 20, stearyltrimonium chloride, citric acid PH adjuster and antioxidants, spinosyn A, and water are also present.

Propylene glycol (claim 16) is also envisioned @ example 2 with spinosad, the instant 85:15 spinosyn A:D (col.3, top), at .25%. Sodium Hydroxide is at col.9, 3 ;instant claims 21, Claim 1 solvents include hexyleneglycol (example 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-9,12,14-19,21-23, & 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder 6,063,771 in view of Kassebaum et al - 6,933,318, Vermeer-565,397 & Kang- et al 6,106,815.

Snyder ( see above) provides lice control compositions, but not of each of the claimed components. KASSEBASUM also shows Lice targeted (col. 1, lines 8-10) with Spinosyns, Spinosads, (col. 4, top), stabilized (col 4, line 17-19). Stabilizers as Miscibilizing agents & spreading agents, & esters of long chain fatty acids (IPM), solvents (col. 4, 5) including benzyl alcohol, & antioxidants, including the instant phenolic forms, but generically claimed, viscosity modifiers, are disclosed as inclusive of the instant agents. Also taught is solubilization of S pinosyns (col. 5, top 2 paragraphs, line 57-line 3, col. 6).

Vermeer is cited to show BHT is a common Antioxidant (col. 41, lines 22-33), that of Kassebaum & of instant claim 20, in topical formulations (col. 89 ) with propylene glycol, water, PH adjuster, viscosity adjuster- conditioning agents, suspending agents, thickeners, water, surfactants are all seen as art recognized components of shampoos-conditions, as exemplified by Vermeer (col. 14, lines 42-50), along with moisturizers (col. 30-31) equivalently PEG, silicones, waxes- cetyl and stearyl alcohol.

Kang shows shampoos are advantageously enhanced with the addition of PVM/MA (summary). The particle size isn't mentioned, but since the compound is the same , so is the size.

Art Unit: 1615

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize Compositions of Snyder, to modify with ingredients to provide improved stability & to add art known antioxidant's and adjuvant & excipient components as desired in order to optimize stability, aesthetics, spreadability, reduce irritation, toxicity, & incompatibility with added ingredients.

Vermeer teaches one having ordinary skill in the art would be motivated to perform this modification in order to have softer, smoother, thicker, moister shampoos, lotions and topical formulations., while Kang shows PVM/MA superior to other stabilizers, thus obvious to the artisan to substitute in the formulations of Snyder. The selection of each ingredient is a result effective parameter chosen to obtain the desired effects. It would be obvious to vary the nature amount of each ingredient to optimize the effects desired, and the use of ingredients for the purposes for which they are known to be used is not a basis for patentability.

There is no unusual and/or unexpected results obtained since the prior art is well aware of the use of cosmetic ingredients and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability.

Applicant has not provided any objective evidence of, nonobvious or unexpected results that the administration of the particular ingredients' or forms or concentrations provides any greater or different level of prior art expectation as claimed.

Claims 1,4-9,11-23,26 & 75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent

Art Unit: 1615

No. 6,727,228. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent encompasses the instant claims

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

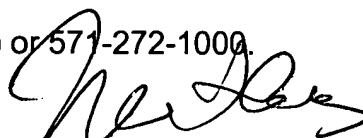
Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619.

The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NEIL LEVY  
Primary Examiner  
Art Unit 1615

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